PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61F 5/453, A61M 25/00, 25/16 // A61L 29/00, A61M 25/02

A1

(11) International Publication Number: **WO 96/29963**

(43) International Publication Date: 3 October 1996 (03.10.96)

(21) International Application Number: PCT/US95/07979

(22) International Filing Date: 22 June 1995 (22.06.95)

(30) Priority Data:
08/414,486 31 March 1995 (31.03.95) US

(71) Applicant: MENTOR CORPORATION [US/US]; 5425 Hollister Avenue, Santa Barbara, CA 93111 (US).

(72) Inventors: MUNSON, Keith, G.; 6599 Kurtz Lane, Eden Prairie, MN 55346 (US). WELCH, Daniel, P.; Route 33, Box 335B, Zimmerman, MN 55398 (US). WOESSNER, Roger, J.; 1858 Lincoln Avenue, St. Paul, MN 55105 (US).

(74) Agent: BUHARIN, Amelia, A.; Larkin, Hoffman, Daly & Lindgren, Ltd., 1500 Norwest Financial Center, 7900 Xerxes Avenue South, Bloomington, MN 55431 (US).

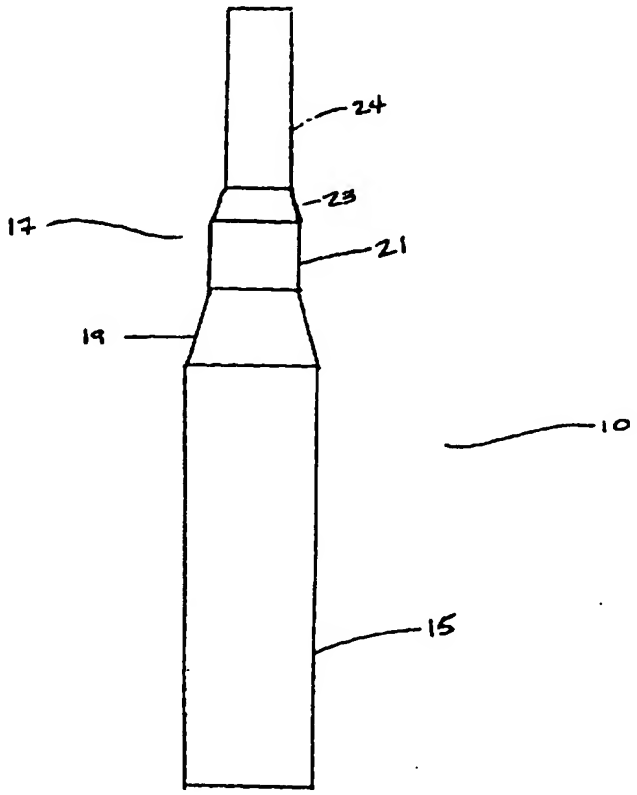
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, UZ, VN, ARIPO patent (KE, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: A MALE CONDOM CATHETER, A METHOD FOR MAKING A MALE CONDOM CATHETER AND A MALE CONDOM CATHETER PRODUCED BY THE METHOD

(57) Abstract

A male condom catheter (10) includes a conical portion (17) and a sleath portion (15), both portions comprising at least about 90 % biocompatible polyurethane. The conical portion (17) includes a cone subsection (19) merging with a surge chamber/anti-kink mechanism subsection (21) which then merges with a neck subsection (23) provided for connection with a tube or conduit (24) for urine passage to a collection bag. The present invention also provides a method for making a male condom catheter and a male condom catheter produced by the method. The method includes dipping a mandrel in a liquid state polyurethane formulation, withdrawing the mandrel, curing to form a conical portion, dipping the mandrel in a second liquid state polyurethane formulation, withdrawing the mandrel and curing to form the sheath portion, thus forming the male condom catheter.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

A male condom catheter, a method for making a male condom catheter and a male condom catheter produced by the method.

1. Field of the Invention

The present invention relates generally to a male external catheter, or condom catheter, and more particularly, to an external male biocompatible polyurethane catheter including a sheath portion and a conical portion as a one piece unit and a method for making the one piece male condom catheter.

2. Description of the Prior Art

It is well known that over-hydrated skin is more susceptible to penetration by chemical irritants, thus causing irritations of the skin such as rashes, sores, swelling and the like. Further, with the use of occlusive materials such as "nonbreathable" tapes used in wound dressings or extended wear external male condom catheters, it is known that increases in the skin causes the skin to become soft or macerated which can lead to skin breakage upon tape or external catheter removal.

In connection with a male urinal device of the type using a urine collection receptacle worn on the body or near the body, it is common to use a sheath of flexible material place over the penis and connected to the receptacle with a tube or other form of flexible conduit. Since urinal devices must be worn for extended periods of time, it is customary for the sheath of such devices to be flexible to allow for patient comfort. It is also desirable for the sheath to possess high moisture transmission because some patients develop skin irritations such as swelling, rashes, sores, etc. due to skin contact with excess moisture, nitrates and protein constituents from urine decomposition as well as from chemicals contained in commonly used materials known in the art, such as rubber latex, for example.

U.S. Patent No. 4,475,910, entitled *Male Condom Catheter Having Adhesive Transfer On Roller Portion*, to Conway et al. discloses a male urinal device having a laminated sheath with an inner layer of latex rubber and an outer layer of silicone rubber. Adhesive is stored between the inner and outer layers when the sheath is rolled. As the sheath is unrolled about a penis, adhesive is released from the outer layer and adheres to the inner layer. Upon pressing the sheath to the penis, a leak-free bond is created.

U.S. Patent No. 4,885,049, entitled *Method of Manufacture of an External Catheter for Male Urinary Incontinence*, to Johannesson (hereinafter " '049") discloses a method of making an external male urinal device having a body portion, including an internal adhesive component and an external cover layer; both are prefabricated components. This disclosure specifically avoids the use of components in a liquid state. Further, the body portion, or sheath, is manufactured as a soft, thin-walled single layer component, preferably latex or synthetic rubber.

U.S. Patent No. 4,626,250, entitled *Male Urinary Collection System and External Catheter Therefor*, to Schneider (hereinafter " '250") discloses an external male urinal device and a method for making the same, wherein the catheter is formed in a dipping process which includes a preliminary step of stretching a pre-formed tubular member over a dipping form. The end of the tubular form which is to become a distal tapered opening is treated so that latex will not adhere thereto upon dipping the remainder of the tubular form in a latex bath to form the outer sheath. The adhesive pad is preferably a synthetic or natural rubber and can also be improved with a minor proportion of polyacrylamide resin. These chemicals will come to rest on the skin upon application of the catheter to a patient.

U.S. Patent No. 5,376,085, entitled *External Urinary Catheter having Integral Adhesive Means*, to Conway et al. (hereinafter " '085") discloses a method of making a male external silicone catheter having an integral acrylic adhesive affixed to the catheter during processing. The adhesive must be of the type that at least partially cross-links

with the silicone catheter during a vulcanization step which occurs when the silicone catheter is in contact with the adhesive. The silicone and the adhesive will contact the skin during use.

It is known to those skilled in the art that many patients develop skin irritations including rashes, sores, overly tender skin etc. with physical exposure to latex or other natural rubber products, as stated hereinbefore, regardless of whether or not the contact between the skin and the latex is made directly or indirectly through an adhesive layer such as that disclosed by the '910 and '250 patents. Further, as rubber latex is opaque, it is difficult to detect any developing skin irritations until patient discomfort develops or when the sheath is removed.

The rubber latex sensitivity phenomenon appears to be affecting the product choices of clinicians and consumers. Silicone catheters, such as (CLEAR ADVANTAGE)™ by the Mentor Corporation, are of tremendous appeal to users because the skin beneath the condom catheter is visible through the sheath. However, some patients' skin also macerate due to low moisture transmission of the silicone. In order to address patients experiencing skin maceration accompanying the use of silicone condom catheters or allergic reactions to rubber latex, it is desirable to utilize a catheter which exhibits high moisture transmission and a low level of chemicals inherent in the sheath material. Further, the cone portion must be flexible enough to withstand insertion of a connecting portion to the receptacle but yet be durable enough to withstand pressure due to excess urine which may accumulate within the catheter. It is further desirable that the sheath and the cone portion are as one unit to eliminate leakage and to accommodate both ambulatory and non-ambulatory patients desiring longer wear external catheters, wherein skin integrity may be examined without catheter removal.

The present invention overcomes the apparent problems and attendant disadvantages associated with male condom catheters formed from rubber latex, other synthetic rubber products or silicone.

SUMMARY OF THE INVENTION

The present invention is directed to a one piece male external condom catheter that addresses the incontinence management needs of male patients who are sensitive to rubber latex, silicone or other rubbers. More particularly, the preferred embodiment of the present invention includes a one piece condom catheter comprising a conical portion and a sheath portion, wherein both portions are produced from liquid-state biocompatible polyurethane. The present device is particularly advantageous in that the male condom catheter is produced from polyurethane which effectively eliminates the skin irritation problems normally associated with rubber latex sensitivity and skin breakdown due to exposure to excess moisture. Another feature of the present device is that it retains the feel, structure and inherent flexibility characteristics of rubber latex, silicone or other rubbers. Still another feature is the clear colorless appearance desired by physicians and consumers. A release coating and an adhesive may also be applied to the sheath surface.

Yet another feature of the present device is that the lowest practicle manufacturing limit for sheath thickness is less than half of the lowest practicle limit for standard silicone sheath thickness. The thinner polyurethane sheath of the present invention has increased "breathability," durability, user comfort and ease in examining skin condition beneath the sheath without sheath removal.

The present invention includes a method for making a male condom catheter device. The conical portion and the sheath portion are produced as a single unit from liquid-state polyurethane. This eliminates the uncertainty of affixing catheter portions composed of different materials which may result in faulty junctions therebetween.

The method comprises dipping a mandrel of a desired shape in a first polyurethane formulation; withdrawing the mandrel at a predetermined rate so that a first conical section is formed on the mandrel; curing the first section; dipping the mandrel including the first portion in a second polyurethane formulation; withdrawing the mandrel

at a predetermined rate so that a second sheath section is formed on the mandrel and integrally affixed to the first portion; and curing the second section. The steps of dipping and curing the conical portion may be repeated such that a predetermined conical portion thickness is obtained. The steps of dipping and curing the sheath portion may be repeated such that a predetermined sheath portion thickness is obtained.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a male condom catheter device of the present invention; and

FIG. 2 is a flow diagram indicating the method for making the male condom catheter in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to FIG.1, a male condom catheter in accordance with the present invention is designated generally as **10**. Device **10** is preferably comprised of a condom portion in the form of a sheath or a sleeve **15** integrally affixed to a conical portion **17** at cone **19**. Conical portion **17** more preferably includes cone **19** merging with a surge chamber/anti-kink mechanism **21** which then merges with a neck **23**. Neck **23** connects with a tube **24**. Surge chamber/anti-kink mechanism **21** may also serve as a backflow prevention device for tube **24**, which is then connected to a urine collection receptacle via flexible conduit or tubing (not shown) . It will be understood by those skilled in the art that device **10** is not limited to the particular embodiment illustrated, and that other combinations of elements including, but not limited to, constrictions and bulbous surge chambers can be added to device **10** without departing from the spirit and scope of the present invention. Such elements, including those illustrated in FIG. 1, may assume various shapes or be arranged in an order other than that illustrated.

As indicated in FIG. 2, male condom catheter device **10** is made by preheating a mandrel (not shown) preferably at a temperature from between about 40 deg. C. to about

60 deg. C for a time sufficient to uniformly preheat the mandrel. Preheating the mandrel is an optional step in the present invention, although preheating facilitates mandrel wetting in subsequent dipping steps. In the present embodiment, the mandrel was preheated at about 50 deg. C. for about 10 minutes. The preheated mandrel is dipped in a first conical polyurethane formulation. The first polyurethane formulation comprises at least about 90% liquid-state biocompatible polyurethane and about 10% of a liquid-state polyurethane thickener. More preferably, the first formulation comprises at least 95% liquid-state polyurethane and about 5% liquid-state polyurethane thickener. Most preferably, about 99% polyurethane and about 1% polyurethane thickener are used. The liquid-state polyurethane utilized must be suitable for medical purposes and is readily available from various sources, such as Polyurethane Specialties Company, Inc. or Miles Inc.

The polyurethane thickener addition to the first conical formulation imparts durability to the final conical portion The conical portion must be durable enough to withstand the tension of inserting and removing tubing which connects the male condom catheter to a urine receptacle and the pressure due to excess urinary pressure which may accumulate within the catheter. The conical portion must also be flexible for patient comfort as the body shifts. While not being bound by theory, it is believed that the polyurethane thickener increases the polyurethane chain lengths resulting in a thinner yet durable conical portion. The polyurethane thickener utilized in the present embodiment is (PMS 836)™ from Polyurethane Specialties Company, Inc. Other polyurethane chain extenders known in the art may also be utilized, such as polyalkene glycol ethers, for example.

Once the mandrel is coated with the first polyurethane formulation, the mandrel is withdrawn from the first formulation at a predetermined rate, which determines the thickness of the conical section layer that remains on the mandrel for further processing. The rate utilized in the present embodiment is about 4 inches per minute for five minutes.

A faster rate would produce a thinner layer, while a slower rate would produce a thicker layer.

The mandrel including the conical section is cured. The temperatures and times of curing are related to the extent that lowering the curing temperature requires longer curing times. While not being bound by theory, it is believed that curing in a single high temperature step would cause the polyurethane carrier (either water or a solvent) to evaporate too rapidly by escaping through bubbles in the polyurethane matrix, which then yeilds small holes in the final catheter product. In the present embodiment, curing takes place over a series of increasing temperatures ranging from between about 60 deg. C. to about 190 deg. C. for about 40 minutes. The mandrel including the conical section is cured by heating at about 70 deg. C. for about 5 minutes. heating at 80 deg. C. for about 5 minutes, increasing the heat to 95 deg. C. deg. and hold for about 10 minutes and heating at 180 deg. C. for about 20 minutes. The mandrel including the conical section is cooled to about 60 deg. C. for about 10 minutes.

The dipping and curing steps may be repeated until a desired conical portion thickness is obtained. A conical portion thickness of about 0.32 inches was found to retain flexibility required for patient comfort.

The sheath portion may be formed by dipping the mandrel including the cured conical portion in a second sheath polyurethane formulation. The second formulation comprises at least about 90% biocompatible polyurethane. The second polyurethane formulation may utilize the same biocompatible polyurethane as in the first conical formulation or it may be any comparable equivalent thereof. Preferably, the second sheath formulation comprises at least about 93% biocompatible polyurethane, about 6% wetting agent and about 1% defoaming agent. More preferably, the wetting agent is selected from the group consisting of emulsifiers, surfactants and combinations thereof.

The term "wetting agent" is generally applied to any substance that increases the ability of an aqueous solution to displace air from a liquid or a solid surface. In the present invention, it is important to displace air pockets which may exist on the mandrel surface. Upon dipping the mandrel in the second polyurethane solution, air pockets which are not displaced translate into irregularities in the final sheath portion which are detrimental to sheath durability and integrity.

In the present invention, a surfactant is added to the second polyurethane formulation to decrease the interfacial tension between the liquid polyurethane and the solid mandrel surface to facilitate evenly coating the mandrel. Further, it is also desirable to reduce the surface tension of the liquid polyurethane because the spreading ability of an aqueous liquid on a solid surface is directly related to the reduction of surface tension in that liquid. Surfactants used in the present invention include those which are suitable for liquid state aqueous thermoplastic resin applications and can be selected from the group consisting of organic surfactants, organosiloxanes and silicone-based surfactants. Organic surfactants include, but are not limited to, nonyl phenols, fatty acid ethylene oxide condensates, alkylene oxide block co-polymers and diols. For example, the surfactant utilized in the present embodiment is (SURFYNOL)™, from Air Products and Chemicals, Inc.

Emulsifiers generally stabilize a liquid system which comprises two immiscible liquids. The type of emulsifier used depends on the type of emulsion to be stabilized. Generally, two types of emulsions exist: an oil-in-water (o/w) where the water is the continuous phase with an oil dispersed within it and a water-in-oil (w/o) where water is dispersed within a continuous oil phase. While not being bound by theory, it is believed that an emulsifier stabilizes an emulsion because the emulsifier adsorbs at the liquid-liquid interface as an oriented interfacial film by performing several functions: 1) reducing the interfacial tension between the two liquids and thus the thermodynamic instability of the system and 2) decreasing the rate of coalescence of the dispersed liquid particles. Emulsifiers suitable for the present invention include those which are suitable

for aqueous thermoplastic resin emulsification, such as alkali soluble emulsifiers. For example, the emulsifier utilized in the present embodiment is the acrylic copolymer (ACRYSOL ASE-95)™.

While not being bound by theory, it is believed that the addition of the emulsifier and surfactant decrease the surface tension of the polyurethane formulation and decrease the interfacial tension between the formulation and the mandrel. These reductions facilitate uniform mandrel coating upon dipping the mandrel in the second formulation.

In addition, an antifoaming agent/defoamer may be added to the second polyurethane formulation. Antifoaming agents appear to counteract the foam stabilizing effect of the surfactant by becoming part of the surface film. While not being bound by theory, it is believed that the addition of a defoamer substantially eliminates surface elasticity and thus decreases the formation of air bubbles upon mixing. It is essential in the present invention that substanially no air bubbles are present in the second formulation because air bubbles may result in holes or tears in the sheath portion of the male condom catheter. The defoamers include those which are suitable for viscous aqueous systems, such as latex or thermoplastic systems. The defoamer utilized in the present embodiment is (DEE FO 97-3)™ from Ultra Additives, Incorporated. Thus, most preferably, the second polyurethane formulation comprises about 93% biocompatible polyurethane, about 1% surfactant, about 5% emulsifier and about 1% defoaming agent.

Once the mandrel including the first portion is coated with the second polyurethane formulation, the mandrel is withdrawn from the second formulation at a predetermined rate, which determines the thickness of the sheath section layer that remains on the mandrel for further processing. The rate utilized in the present embodiment is about 4 inches per minute for 7 minutes.

The mandrel including the conical portion and the sheath section is cured. As in curing the conical section, the temperatures and times for curing the sheath section are

related to the extent that lower temperatures require longer time periods for curing. In the present embodiment, curing takes place over a series of increasing temperatures ranging from between about 70 deg. C. to about 190 deg. C. for about 30 minutes. The mandrel including the conical portion and the sheath section is curing by heating at about 80 deg. C. for 5 minutes, heating at about 95 deg. C. for about 5 minutes, heating at about 115 deg. C. for about 5 minutes and heating at about 180 deg. C. for about 15 minutes. The mandrel including the conical portion and the sheath section is cooled to about 60 deg. C.

As with the conical portion, the dipping and curing steps for the sheath portion may be repeated until a desired sheath portion thickness is obtained. In the present embodiment, it was found that a sheath portion thickness of about 0.011 inches provided desirable comfort and physical characteristics, as discussed below.

Once the desired sheath section thickness is obtained and cured, a release coating and/or an adhesive coating may also be applied to male condom catheter **10**.

Polyurethane sheaths possess a moisture vapor transmission rate substantially equivalent to that found with normal human skin perspiration. Uncovered skin has a moisture transmission rate of about 41.3 +/- 3.5 ug/cm^2/min. while a polyurethane sheath, having a thickness of about 8.5 mils., has a moisture transmission rate of about 41.23 ug/cm^2/min. Further, it was found that the moisture vapor transmission value for the present invention improves both comfort and function. For example, it was found that a moisture vapor transmission at least about equal to that found in skin, i.e., about 41 ug/cm^2/min. avoids both skin maceration and excess moisture retention in an adhesive layer on the sheath portion.

Additionally, the physical characteristics of the polyurethane sheath having a thickness from between about 3 mils to about 4 mils were compared to those of a standard silicone sheath having a thickness from between about 8 mils to about 9 mils.

Both sheath types possess the desirable clear colorless quality. The table below summarizes those results.

TABLE 1

Test	Polyurethane Sheath	Silicone Sheath
Sheath Wall Thickness	3 - 4 mils	8 - 9 mils
Percent Elongation	792 - 1549*	300 (before break)
100% Modulus psi	223 - 331	208 - 354
Tensile at Break psi	826 - 3089*	800
Moisture Vapor Transmission	> 75**	38**

*Elongation/Tension testing instrument stopped at maximum elongation, 2 out of 12 samples did not break at maximum instrument elongation.

**The units represent grams/100 in^2/24 hours at 95% relative humidity.

The polyurethane sheath is up to about 5 times more stretchable and durable than the silicone sheath, as shown by the percent elongation and the pounds per square inch required to break the sheath upon stretching. Therefore, the polyurethane sheath is stronger, more moisture vapor transmissive and yet is less than half as thick as the silicone sheath.

This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as required. However, while a particular embodiment of the present invention has been described in detail, it is to be understood that various alterations, modifications and substitutions can be made therein without departing from the spirit and scope of the present invention, as defined in the figures contained therein and in the claims which follow. For example, one skilled in the art will appreciate that the foregoing embodiment is capable of being produced using varying polyurethane curing temperatures and times.

We Claim:

1. A male condom catheter, comprising:

(a) a conical portion comprising at least about 90% wt. biocompatible polyurethane; and

(b) a sheath portion integrally affixed to the conical portion, the sheath portion comprising at least about 90% wt. biocompatible polyurethane.

2. The male condom catheter of claim 1, wherein the conical portion further comprises from about 98% to about 100% wt biocompatible polyurethane and from about 0% to about 2% wt polyurethane thickener.

3. The male condom catheter of claim 1, wherein the sheath portion further comprises:

(a) from about 93% wt to about 100% wt. biocompatible polyurethane;

(b) from about 0% wt. to about 6% wt. wetting agent; and

(c) from about 0% wt. to about 1% wt. defoaming agent.

4. The male condom catheter of claim 3, wherein the wetting agent is selected from the group consisting of emulsifiers, surfactants and combinations thereof.

5. A method for making a male condom catheter of biocompatible polyurethane having a conical portion and a sheath portion integrally affixed thereto, comprising the steps of:

(a) dipping a mandrel having a desired shape of the condom catheter in a first polyurethane formulation;

(b) withdrawing the mandrel at a predetermined rate so that a first conical section of a desired thickness is formed;

(c) curing the first section;

(d) dipping the mandrel including the first portion in a second polyurethane formulation;

(e) withdrawing the mandrel at a predetermined rate so that a second sheath section of a desired thickness is formed and integrally affixed to the first section; and

(f) curing the second section.

6. The method of claim 5, wherein prior to step (a) further comprises preheating the mandrel having a desired shape of the condom catheter at a temperature from between about 40 deg. C. to about 60 deg. C. for a time sufficient to uniformly preheat the mandrel:

7. The method of claim 6, wherein curing the first conical section of step (c) further comprises heating the mandrel from step (b) in a series of increasing temperatures ranging from between about 60 deg. C. to about 190 deg. C for about 40 minutes and cooling the mandrel to about 60 deg. C. after heating.

8. The method of claim 7, wherein curing the second sheath section of step (f) further comprises heating the mandrel from step (e) in a series of increasing temperatures ranging from between about 70 deg. C. to about 190 deg. C. for about 30 minutes and cooling the mandrel to ambient temperature after heating.

9. The method of claim 8, wherein steps (a), (b) and (c) are repeated until a predetermined conical portion thickness is obtained.

10. The method of claim 9, wherein steps (d), (e) and (f) are repeated until a predetermined sheath portion thickness is obtained.

11. A male condom catheter produced by the methods of either claims 5 or 10.

12. The male condom catheter of claim 11, wherein the sheath portion of the male condom catheter has a moisture vapor transmission rate of about 41 ug/cm^2/minute.

FIG. 1

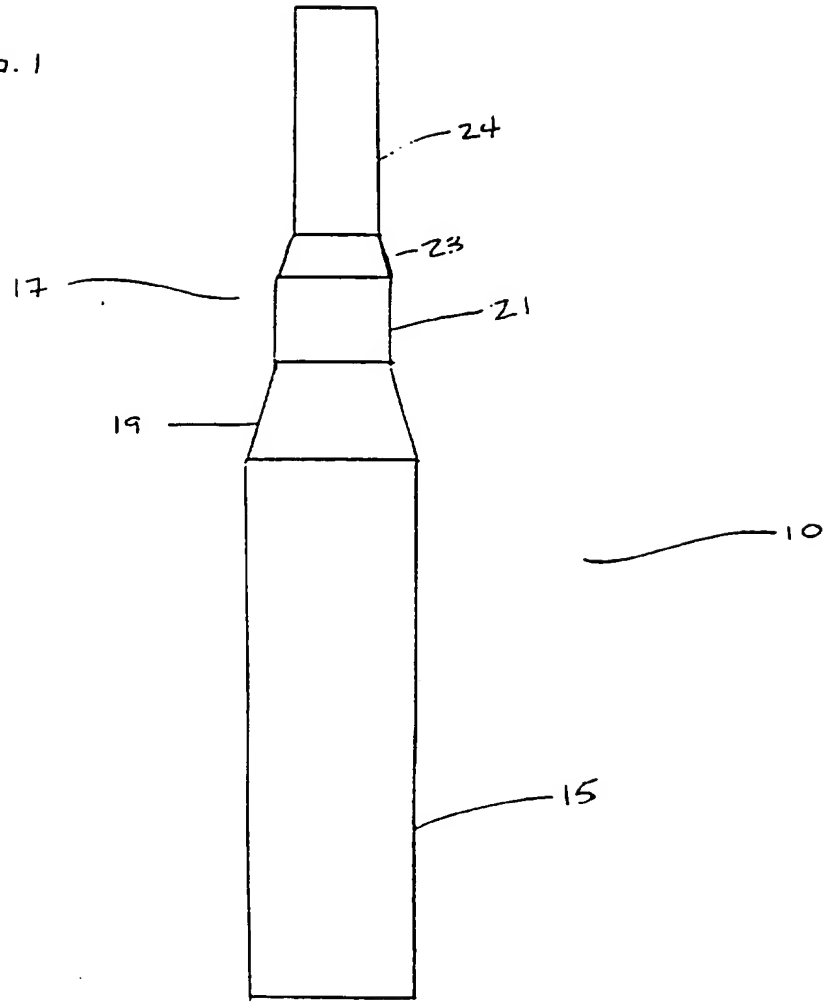
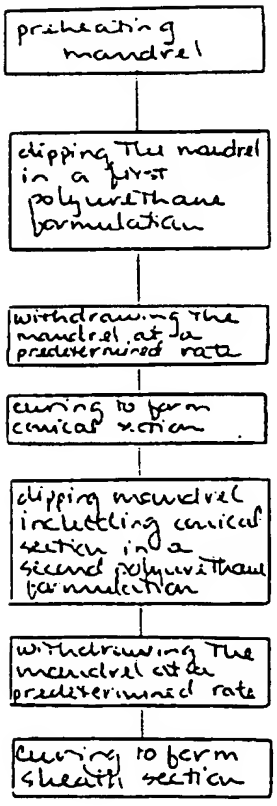

24
23
17
21
19
10
15

FIG. 2


preheating mandrel
dipping the mandrel in a first polyurethane formulation
withdrawing the mandrel at a predetermined rate
curing to form conical section
dipping mandrel including conical section in a second polyurethane formulation
withdrawing the mandrel at a predetermined rate
curing to form sheath section

INTERNATIONAL SEARCH REPORT

Interr ·nal application No.
PCT/US 95/07979

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/453, A61M 25/00, A61M 25/16 // A61L 29/00, A61M 25/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F, A61L, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DIALOG, EPOQUE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP, A2, 0595500 (BECTON DICKINSON AND COMPANY), 4 May 1994 (04.05.94), Medical devices, most preferably a catheter, made from biocompatible polyurethane. --	1-12
Y	GB, A, 2152380 (DOWNS SURGICAL PLC), 7 August 1995 (07.08.95), An external male urinary device made from a single piece of polyurethane. --	1-12
Y	US, A, 4475910 (CONWAY ET AL), 9 October 1984 (09.10.84), An male condom catheter made by dip forming. --	1-12

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search
15 December 1995

Date of mailing of the international search report
17. 01. 96

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+ 31-70) 340-3016

Authorized officer
Leif Vingård

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 95/07979

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4626250 (SCHNEIDER), 2 December 1986 (02.12.86), A male external catheter with tapered neck section. --	1-12
Y	US, A, 4722344 (CAMBRON ET AL), 2 February 1988 (02.02.88), A catheter made from polyurethane. --	1-12
Y	US, A, 5374704 (MÜLLER ET AL), 20 December 1994 (20.12.94), Biocompatible polyurethane. --	1-12
Y	US, A, 5376085 (CONWAY ET AL), 27 December 1994 (27.12.94), External urinary catheter having a unitary construction and a step-wise tapered (11b, 17a,17b) design. --	1-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

30/10/95

International application No.
PCT/US 95/07979

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A2- 0595500	04/05/94	NONE	
GB-A- 2152380	07/08/95	GB-A,B- 2106395	13/04/83
US-A- 4475910	09/10/84	CA-A- 1183750	12/03/85
		DE-A,C,C 3236396	14/04/83
		GB-A,B- 2106784	20/04/83
		JP-A- 58130037	03/08/83
		US-E- RE33206	01/05/90
US-A- 4626250	02/12/86	AT-B- 388289	26/05/89
		AU-B,B- 540628	29/11/84
		AU-A- 8294282	09/12/82
		CA-A- 1176530	23/10/84
		DE-A,C,C 3220791	30/12/82
		FR-A,B- 2507081	10/12/82
		GB-A,B- 2099706	15/12/82
		JP-C- 1712213	11/11/92
		JP-B- 3065976	15/10/91
		JP-A- 58001445	06/01/83
		NL-A- 8202283	03/01/83
		SE-B,C- 456723	31/10/88
		SE-A- 8203249	06/12/82
		US-A- 4581026	08/04/86
US-A- 4722344	02/02/88	AU-B,B- 609403	02/05/91
		AU-A- 7511087	22/12/87
		CA-A- 1334120	24/01/95
		DE-A- 3773209	24/10/91
		EP-A,B- 0309463	05/04/89
		JP-T- 1502720	21/09/89
		WO-A- 8707155	03/12/87
US-A- 5374704	20/12/94	CA-A- 2111926	24/06/94
		DE-A- 4315173	30/06/94
		EP-A- 0603675	29/06/94
		JP-A- 6228265	16/08/94
US-A- 5376085	27/12/94	AU-B- 659117	11/05/95
		AU-A- 9094091	11/06/92
		CA-A- 2095030	10/05/92
		DE-D,T- 69107470	14/09/95
		EP-A,B- 0556325	25/08/93
		JP-T- 6501412	17/02/94
		US-A- 5176666	05/01/93
		US-A- 5334175	02/08/94
		WO-A- 9208426	29/05/92